

The Expanding Purview: Institutional Review Boards and the Review of Human Subjects Research

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Abstract

The implications of the institutional review board (IRB) system's growing purview are examined. Among the issues discussed are whether IRBs are censoring research and whether the IRB review process fundamentally alters the research that is being conducted. The intersection between IRB review and free speech is also explored. In general, it is argued that the review system for human subjects research (HSR) should be modified in order to limit the scope of IRB review.

Introduction

The definition of human subjects research seems to be broadening, as is indicated by the increasing number and variety of projects that have been reviewed by an institutional review board (IRB). Oral historians, academic journalists, and other "non-biomedical" researchers have had their work scrutinized by IRBs. However, an expanding purview can create difficulties for the IRB system. The purpose of this article is to articulate several of the key problems that a growing purview can generate and to outline recommendations that may help to address the issue.

An Overview

In accordance with federal regulations, research with human subjects that is federally funded or supports an application for a product to be approved by the Food and Drug Administration (FDA) must be reviewed by an institutional review board (IRB). IRBs must decide whether research conducted at their home institution needs to be reviewed, and if so, what type of review is required. One of the key questions in the review process is determining whether a project counts as human subjects research (HSR). Historically, IRBs primarily focused their attention on biomedical research. Yet, in accordance with federal guidelines, IRBs have a responsibility to review any form of human subjects research that receives federally funds, including various forms of social and behavioral research. This mandate has generated much controversy. Moreover, many IRBs at universities have decided to assess research protocols that are not federally funded and do not support FDA

applications, which raises questions about whether this action is consistent with the intent of federal guidelines (Shweder, 2006).

Arguments between researchers and IRBs occur, for example, over which specific forms of social and behavioral research require review. IRBs have assessed research projects from anthropology, ethnography, academic journalism, oral history, and other humanities and social science disciplines that have not traditionally fallen under IRB purview. Usually, to their dismay, these researchers have been told that they cannot proceed with their work until they submit a protocol to the IRB and have it approved. (Jaschik, 2005; Brainard, 2001; Shea, 2000). Debates have been ongoing for some time about whether the IRB system is well designed to assess social science and humanities research (Gunsalus et al., 2006; Howard, 2006; Hamburger, 2004).

It does not take too long to appreciate how operating with an expansive definition of HSR, which if understood broadly enough could include fields such as oral history and journalism, can lead to the danger of a "slippery slope." In principle, any form of inquiry involving a human being, at least of the federally funded variety,¹ could come under the purview of an IRB. Yet there are good reasons to resist going down that path. The "mission creep"² of the IRB system has its share of hazards.

A consensus has yet to form regarding whether many different types of "non-biomedical" research protocols should be reviewed. Monitoring the work of academic journalists, for example, is not a standardized and universal practice across the IRB system. As a result, this can generate confusion and uncertainty for researchers, especially those who are working on multi-institutional projects where the IRBs can operate with dissimilar views on what counts as HSR. On a related note, IRBs can have conflicting opinions regarding which projects qualify for expedited review, which is determined in part by perceptions of whether a protocol poses "no greater than minimal risk."³ Under federal regulations, research that is classified as minimal risk can be reviewed by an IRB chair (or designee) and does not require review by the full committee.

Expertise Limitations

Critics of the expanding scope of IRB review often complain that IRBs might not have the requisite expertise to evaluate competently the vast array of protocols that they confront. IRBs are largely composed of individuals in fields relating to medicine.⁴ Consequently, because of their composition, it is debatable whether IRBs can, for example, effectively assess "non-biomedical" protocols. According to Cary Nelson, "the growing literature on campus IRBs shows again and again that boards assembled to supervise biomedical research often haven't a clue about the culture of history or anthropology or literature departments" (Nelson, 2003). Nelson's assertion is overstated, but it does highlight the issue of whether IRBs are taking part in an epistemically sound practice. In other words, it is plausible that difficulties could emerge if IRBs examine a research protocol and yet do not have members within the respective field(s) of inquiry.

Following the underlying logic of the peer review system for grants and publications, there are good reasons why experts in the relevant field are sought out to assess the work of their colleagues.⁵ Correspondingly, it can be problematic if one tries to determine what counts as a suitable methodology in a field that is outside the bounds of that person's area of expertise. For example, IRB members could face a daunting epistemic challenge considering that they are not typically ethnographers, anthropologists, or journalists themselves. Murray Wax, a professor of anthropology, stated while testifying before President Clinton's National Bioethics Advisory Commission that:

The gravest ethical problem facing the people studied by anthropological research is posed by unknowing and overzealous IRBs and by governmental regulators attempting to force qualitative ethnographic studies into a biomedical mold (NBAC, 2000, p. 95).

Wax goes on to make the case that if IRBs "bureaucratically apply the regulations to all projects," their efforts can be corrosive to research and actually harm human subjects (NBAC, 2000, p. 100). If his claims are justified, then an IRB might not be the best forum for evaluating ethnographic studies and other projects where informed consent, control groups, and placebos are not the norm.

Scholars also argue that differing conceptions of risk can become a stumbling block when IRBs assess the work of social scientists (De Vries et al., 2004, p. 352). Whereas IRB members may have a clear sense of the types of risks that can stem from testing a prescription drug, they are not usually as familiar with the risks arising from a sociological study. Depending on which specific details are eventually published, subjects within a sociological study may be able to identify one another, which can raise privacy and confidentiality concerns (Tolich, 2004). It is reasonable to ask whether risks will properly be identified and addressed by an IRB if sociologists are not serving as members. Similarly, if IRB members have not participated as researchers on a study that examines the behaviors of individuals in an Internet "chat room," one can ask whether they will be proficient at identifying the associated risks. It should be kept in mind that this is only a small sample of the types of sociological protocols that IRBs do and could eventually confront.

It is worth pointing out, however, that IRBs have some ways of addressing the expertise problem. First, IRB members may develop the requisite skill reviewing similar types of protocols. As ethnographic research is confronted with more regularity, for example, the argument could be made that IRBs will become more capable of evaluating it. According to the AAUP, "[b]etter representation of social scientists on IRBs can also help make their decisions more credible" (AAUP, 2000). Second, IRBs can make use of outside experts to inform their deliberations, although this is probably done rather infrequently. Third, institutions can form IRBs specifically designated to review social science research.

However, these strategies for dealing with the expertise problem do have shortcomings. As the scope of IRB review expands, it will become a progressively more difficult challenge to enlist a member who is an expert in each of the relevant fields of research that an IRB examines. Moreover, even if it is possible to recruit an expert from each field, it does not necessarily follow that the individual will be able to evaluate competently every form of research taking place in that particular field. Additionally, institutions may not be able to gather together the resources needed to create "non-biomedical" IRBs. Considering that the number and type of highly specialized and technical research protocols involving human participants will just continue to grow over time, the associated expertise problem is likely to compound.

Reshaping Research

Many researchers are uneasy about the constraints imposed by the IRB system, because they claim that IRBs can cause the nature of the work to be fundamentally changed (Feeley, 2007; Katz, 2006). According to Lincoln and Tierney, "[a] variety of strategies have been devised by researchers to overcome persistent rejection by IRBs, including several that actually undermine the work" (Lincoln and Tierney, 2004, p. 222). Although much of the evidence is anecdotal, if researchers alter the nature of the work primarily to avoid the scrutiny of an IRB or to hasten the process of approval, it is a profoundly troubling development.

The structure and/or content of an inquiry could be reshaped if critics are correct that the "biomedical model" is being applied to "non-biomedical" research (Feeley, 2007, pp. 765-766). A case in point is the contention that informed consent can be problematic (AAUP, 2006). For instance, anthropologists argue that obtaining consent from each person in a study could drastically alter what is being observed. What follows is that consent could be a hindrance even when working with competent adults. According to Hoeyer, Dahlager, and Lynoe, "[t]he reluctance to embrace an informed consent requirement might also be related to anthropologists having so many different contacts throughout fieldwork, of varying intensity and importance, that consent from everyone is regarded as a practical impossibility" (Hoeyer et al., 2005, p. 1743).

Jack Katz claims that the insistence on informed consent can transform the methods used for some forms of ethnographic research, or it may even encourage researchers to ignore an IRB's guidelines (Katz, 2006). The authenticity of ethnographic research is often contingent on trying to prevent a researcher's actions and preconceptions from interfering with what is being observed. Informing potential subjects about the nature of the research can undermine the reliability of the results. Thus, undertaking the research could become a futile endeavor. In short, Katz suggests that an IRB's constraints may force ethnographers to go "underground" (Katz, 2006). Along similar lines, Ellis and Earley claim that it may not be appropriate to insist on written consent, which IRBs often do, when conducting "qualitative research" with indigenous populations (Ellis and Earley, 2006). Among the reasons is that the population might not be capable of understanding what they are being asked to read.

What could allay some of the researchers' qualms is that provisions within federal regulations allow for various parts of the consent process to be waived (Common Rule, 2005). Yet disagreements still ensue between IRBs and researchers regarding whether a particular protocol qualifies for a waiver or what type of waiver should be applied. This happens in part because IRBs seek to uphold the autonomy and privacy of subjects in a meaningful way. Thus, the default setting in most cases, and probably rightfully so, is to require consent, but again this can cause difficulties for some forms of research.

Although the complexities relating to consent will not be resolved here, the issue of whether an IRB's requirements fundamentally constrain research requires ongoing analysis. Moreover, the method used to obtain consent is only one of the dimensions of a research protocol that an IRB examines, but it is a crucial dimension. It is illustrative of the tensions that can be unearthed when a particular vision, even if it is a flexible one, of how research should be conducted is applied to evaluate a diverse variety of research projects. Thus, the IRB review process might restructure research in such a way that it changes the nature of the inquiry.⁶

On a related note, satisfying an IRB's requirements could, as a by-product, cause publications resulting from research to be altered. For example, due to privacy considerations, an IRB might insist that unique identifiers are removed from collected data. This can make it rather challenging for anthropologists or sociologists to report on their work within a publication, since they may be limited to describing a studied population in very general and broad terms. Researchers might be restricted from revealing specific details that could permit a reader to identify the population in question. But what could follow is the exclusion of valuable information from the scholarly literature. For instance, as Philip Hamburger notes, personal data collected during an interview might have to be removed before publishing the relevant work (Hamburger, 2004, pp. 305-307). This kind of modification, and others that researchers may be asked to make, can be at odds with publication practices and norms within a professional field. Yet the counterbalancing point, which should not be lost, is that the importance of upholding privacy can outweigh the potential need for disclosing a subject's information.

Halting or Delaying Research

A common objection to expanding the role of IRBs is that essential research might be significantly delayed or not even performed at all. In principle, it is not desirable that the IRB system interferes with the progress of research. The IRB submission and review process can push back the start of a project, perhaps for several months. This can, for example, cause problems for researchers who are trying to meet publication deadlines, trying to earn tenure, or who are conducting research that has strict time limitations, such as observing the behavior of victims following after a natural disaster. According to critics, the IRB system basically forces researchers to obtain a license before proceeding with their work (Feeley, 2007, p. 766).

Quality improvement studies, for example, highlight the problem that important research might be halted because of the IRB review process. For one, uncertainty about whether these studies should be considered HSR can cause delays (Casarett et al., 2000). Further, according to Miller and Emmanuel, obtaining consent for quality improvement studies cannot effectively be done in many cases, which, as a by-product, could entail that conducting the research might violate an IRB's rules (Miller and Emanuel, 2008). But failing to perform the relevant work can have detrimental impacts on patient care. The Office for Human Research Protections (OHRP) recently decided that human subjects research regulations should not apply to a quality improvement study, which investigated catheter-related infections at Michigan hospitals (OHRP, 2008). Yet it remains to be seen whether it is a precedent that will cover future studies.

Researchers across numerous fields voice complaints about the unfairness resulting from having to delay the start of their work, which oftentimes follows from having to develop or restructure a consent form (Keith-Spiegel and Koocher, 2005). In one case, a researcher had to obtain permission from an IRB in order to conduct an interview with his/her own mother (Nelson, 2003). Further, students might not graduate on time if an IRB decides that their work must be reviewed (Brainard, 2001). Some critics allege that these problems create a temptation for researchers to either describe their work in a misleading way or sneak under the IRB's radar in order to avoid scrutiny (Giles, 2005, pp.136-137).

Robert Kerr describes a situation where a student pursuing a graduate degree in communications sought to interview an elderly individual (Kerr, 2006, pp. 397-398). During the process of trying to fulfill the IRB requirements at his university, the person that the student planned to interview passed away (Kerr, 2006, p. 398). The student would likely have had the opportunity to conduct the interview if he had not had to wait for IRB approval. I am not claiming that the IRB acted inappropriately in this case. Rather, it highlights the general point that postponing the start of a project can have serious ramifications.

Of course, the drawback that research might be postponed must be balanced against the reality that various different forms of research, some of which are not typically reviewed by IRBs, can pose non-trivial risks to humans that are involved. The goal of protecting human subjects should not be brushed aside merely so that researchers can proceed with their work. It should also not be forgotten that an effective review can potentially detect flaws and prevent limited resources from being wasted.

A discussion of these issues would be incomplete if we failed to recognize that part of the problem results from the researchers themselves. Researchers play a key role in contributing to some of the difficulties that the IRB system experiences because many of them are not familiar with how IRBs work. The frustration expressed against IRBs often occurs because not all researchers understand the need for IRB review and the regulations that govern the process (Pollick, 2007). Researchers also may not understand how to

prepare a protocol for submission to an IRB. Some of these problems might be overcome if researchers receive instruction about the IRB review process.

The Censorship of Research

A recent controversy is whether researchers avoid some topics because of the difficulty associated with satisfying an IRB (Feeley, 2007, pp. 764-766). Hamburger suggests that politically sensitive or potentially inflammatory research could in effect be censored because of the IRB review process (Hamburger, 2004, pp. 343-352). According to Hamburger, "by requiring excessively somber warnings in informed consent forms—even those for social science research—IRBs can ensure low participation, and in this way can force a halt to research they find objectionable, without formally denying approval" (Hamburger, 2004, p. 302). Hamburger implies that IRBs abuse their power by selectively choosing which research can go forward. If he is correct, this problem can be complicated by the fact that there are few, if any, avenues available to appeal an IRB's decision.

Hamburger's arguments on this point are rather uncharitable to the IRB system. It is not clear that IRBs systematically and deliberately seek to suppress research that they find to be unpalatable. Yet there is plausibility behind the notion that, as a by-product of the review process, controversial types of research might not be performed. A study of domestic violence and drug use certainly has some rather arduous regulatory hurdles to overcome before it is approved. Researchers might become disheartened and thus avoid the subject matter after repeatedly confronting the challenge of trying to receive approval for their work. As the AAUP notes:

[...] [A] description of the challenges of applying IRB reviews to social science research would be seriously incomplete if it ignored the danger to freedom of research—if only through self-censorship—implicit in the requirement that IRBs evaluate the importance of research (AAUP, 2000).

Even if it is not the intention of IRBs, researchers would likely be deterred from pursuing research avenues for which obtaining approval is exceedingly difficult. The danger here is that the pursuit of knowledge is hindered. Regarding the aforementioned example, gathering data about drug use could help facilitate the development of policies used to prevent domestic violence. But if relevant studies grind to a standstill due to self-censorship, it could stifle the policy-making process.

Scarce Resources

The costs associated with reviewing protocols can be fairly significant, especially for institutions that have a medical school (Hyman, 2007, pp. 756-757; Sugarman et. al., 2005). Thus, the resources needed to expand the purview of the IRB system are non-trivial. Institutions will have to take steps, such as creating additional IRBs, increasing the number of members on existing IRBs, and hiring new support staff. Of course, financial considerations should not take precedence over the goal of protecting human subjects. Yet from a practical perspective, it is fairly unlikely that institutions have sufficient resources available to meet the demand of having their IRBs inspect comprehensively every form of research that involves a human being.

According to the Illinois White Paper, "IRB regulation of very low-risk social science and humanities research diverts needed resources from areas of greatest need to those areas with minimal or no risk" (Gunsalus et. al., 2006, p. 16). Although the White Paper's claim is contentious, it does illustrate the point that it can be rather taxing for IRBs to gather together the resources necessary to review the number of protocols that are currently submitted. The problem will magnify if academic journalists, ethnographers, and other

researchers who historically did not submit protocols to an IRB are now required to do so. Granted, we do not want human subjects to be harmed in research but if the White Paper's observations have merit, perhaps it would be more fruitful to keep the focus on protocols that are more likely to pose significant risk.

Journalism and Freedom of Speech

As the scope of IRBs continues to increase, it will have a growing effect on academic journalism departments. Depending on how the work of journalists is described, it could qualify as HSR. An academic journalism project can involve collecting information from interactions with other individuals. Certainly "identifiable private information" is often gathered and then revealed in a publication. A published article can also do non-trivial harm to the individuals mentioned within it. Consider for a moment the impact that false allegations had on Richard Jewell's life, which generates the argument that the pens of journalists greatly damaged his reputation and well-being (Weber, 2006). This insight is applicable to the projects that students and professors undertake in journalism departments, considering the possible ramifications of their work.

According to critics, IRB review of research, in this case journalism projects, could interfere with First Amendment rights (Hamburger, 2004). Kerr suggests that "by and large the speech activities of scholars who utilize journalistic research methods remain fully subject to IRB review before the fact" (Kerr, 2006, p. 395). Along these lines, even though journalism may technically be a form of HSR, requiring journalism students and professors to undergo IRB review can be fraught with problems. Arguably, the practice could be objectionable because it enforces "prior restraint" by restricting speech acts before they occur. Even though their free speech rights are not absolute, journalists do enjoy significant protection under the U.S. Constitution. Thus, reviewing their work could create a legal quandary for the IRB system if it prevents them from exercising their constitutional rights.

The examination of academic journalism projects by IRBs can also raise consistency problems. More specifically, a journalism professor may need to obtain IRB approval before proceeding with a research project, but this is not typically a requirement prior to writing an article for a newspaper. The underlying reasoning here for the distinction is not altogether clear. According to Nelson, "IRBs exempt newspaper journalism in part because they do not dare take on the press" (Nelson, 2007). Regardless of whether Nelson is correct on this point, it is puzzling why different standards would apply to two projects when these projects may in essence amount to being the same kind of work.⁷

Observations and Recommendations

Informed consent is a central linchpin to many of the debates about the IRB system. Organizations such as the National Academy of Sciences have articulated strategies and best practices that may help "non-biomedical" researchers to better understand what is expected of them, especially with regard to consent (NAS, 2003, pp. 81-112). What could also save researchers and IRB members a fair amount of time and energy, something that is repeatedly a source of contention, is simplifying how consent forms are developed. A more streamlined method that guides researchers with regard to constructing a consent form might sidestep many of the conflicts and delays associated with IRB review (Hyman, 2007, pp. 762-764).

Some of the problems with the consent process will not necessarily be resolved even if standardized forms are used. For instance, this kind of proposal must be balanced against the concern that the review process may become too standardized and uniform if similar forms are repeatedly inspected. Yet it is likely better than the alternative where researchers

themselves, with mixed success, try to reinvent the wheel each time by fashioning their own forms. It would be tremendously beneficial if the consent forms used were clear, direct and short enough to allow potential subjects to actually read and comprehend what they are being asked to sign.⁸ On a related note, different templates could be created for different types of research.

Barring a sharp change in federal policy, administrators, compliance officers, and other institutional officials should establish and articulate their institution's standing policy on which types of research, "non-biomedical" or otherwise, merit IRB review. Ideally, all researchers should have a clear sense of whether their work is considered to be a form of HSR in accordance with federal and institutional guidelines. A shared understanding across an institution could alleviate some of the hostility aimed at the IRB system and help to ensure that research proceeds as safely and efficiently as possible.

Further, it is less than ideal that IRBs at different institutions operate with diverging conceptions of which types of research merit review. For example, the work of journalists and oral historians is reviewed by some IRBs but not by others (Howard, 2006). It is understandable that oral historians are frustrated if they do not know how to anticipate whether their work is exempt from review.⁹ Granted that the IRB system is decentralized, but facilitating conversations across different IRBs could remove some of the variability. As a consequence, oral historians and other researchers would more clearly know what to anticipate.

We must also temper our expectations concerning what an IRB can reasonably accomplish. IRBs are frequently understaffed and overworked. In general, they need additional resources to review an ever-growing and increasingly complex collection of protocols. Thus, IRBs may have to pick and choose their battles if they are going to be able to accomplish their mandate with an adequate degree of thoroughness. Given resource limitations, IRBs probably cannot and should not be monitoring every form of research that involves a human being. It would probably be wise, as Adil Shamoo suggests, to divert the attention of IRBs away from low-risk research (Shamoo, 2007). However, it is not always easy to determine, in advance, whether a particular type of research constitutes low-risk or minimal-risk research.

On a related note, a strategy that has been considered is to have separate review tracks for different kinds of research.¹⁰ It is an approach that many universities have implemented. As Laura Stark notes, "IRB subcommittees, which can review lower-risk studies, have moved ethics review into academic departments" (Stark, 2007, p. 784). It could lessen the burden on the IRB system by scrutinizing research protocols at the departmental, or perhaps college, level, thereby bypassing review by the full IRB.

The strategy has some merit, but major hurdles need to be sorted out. For one, it is already a challenge to persuade enough individuals to serve on existing IRBs, and if the review system for research expands, the problem would just grow. The format could also lead to conflicts of interest by having faculty members from the same department examine each other's work. Conversely, one of its key advantages is that we would not merely be allowing researchers themselves to identify the risks of their own work. By having other individuals scrutinize research proposals, unanticipated or under-appreciated risks might be recognized and discussed more consistently. If the judgment is then made that the research poses "greater than minimal risk," it can at that point be sent to a full IRB for review. The approach also has the virtue that individuals with expertise in the relevant realm would directly be evaluating the work of their colleagues. This might address the longstanding criticism lodged against the IRB system that members lack familiarity with some of the methods and norms being assessed.

Another part of the puzzle is to encourage institutions to have conversations about research ethics across the entire curriculum. As Pollick suggests, the IRB approval process might proceed more smoothly if researchers understood at an early point in their career the function of an IRB (Pollick, 2007). It is already part of the culture in the biomedical world to discuss HSR and other ethics-related topics. Graduate students in “non-biomedical” fields should be informed about research ethics as well, including the nature of an IRB and the possible need for IRB review. The National Academy of Sciences, for example, recommends this kind of educational initiative in the social and behavioral sciences (NAS, 2003, p. 169). Even if it turns out that a graduate student in history or journalism does not have to submit a description of his/her research to an IRB, a fuller understanding of the broader ethical implications of the research should follow from a dialogue about the issue. The information will be of use at some point, especially considering that the modern research environment is so interdisciplinary.

Conclusion

Ultimately, professionalism and the critical thinking skills of researchers must be relied on to help ensure that their work is performed in an ethical manner. As the Illinois White Paper astutely notes, “[i]n a system that trusts researchers to behave morally, and can do nothing else, researchers must internalize such values” (Gunsalus et al., 2006, p. 7). It is not possible to evaluate and monitor every form of research involving human participants thoroughly given current constraints. The scope of IRB review needs to be appropriately limited. Even with other review mechanisms being put into place to complement the IRB system, there has to be a point where trust prevails. The integrity of researchers is an essential and irreplaceable component of a thriving research enterprise.

Notes

1. For the purposes of this article, the issue of whether IRBs should review non-federally funded research will not be explored.
2. A pejorative term often used to refer to the IRB system's growing purview; for example, see the Center for Advanced Study's White Paper on the IRB system (Gunsalus et al., 2006).
3. Another key factor is whether the form of research is specifically delineated as qualifying for expedited review under federal guidelines (HHS, 1998).
4. According to a survey by De Vries, DeBruin, and Goodgame, “[...] nearly 70% of boards have 30% or more of their members drawn from biology and medicine” (De Vries et al., 2004, p. 355). The survey had a sample size of 87 IRBs.
5. Of course, the analogy between peer review and IRB review is not exact, since each respective process focuses on different dimensions of research. The procedure for selecting peer reviewers and IRB members is also not equivalent. Yet the point should not be lost that, in order for both types of review to function well, expertise with regard to the type of research being scrutinized is a vital element.
6. But this is not necessarily a bad thing if human subjects are protected from harm.
7. One thing that may distinguish the different projects is the source of funding, but many IRBs already review research that is not supported by federal funds.
8. A likely reason why consent forms have become overly technical and complicated is due to concerns about legal liability. As a by-product, many of the consent forms that result are fairly opaque and cumbersome.
9. According to one report, “most oral history interviewing projects” are exempt from IRB review but not all (Oral History, 2004). This leads to confusion regarding which ones still need to be examined by an IRB.

10. One place where this type of approach has been articulated is within the Illinois White Paper (Gunsalus et al., 2006, pp. 21-22).

References

- American Association of University Professors (AAUP). (2000). Institutional Review Boards and Social Science Research. Retrieved May 8, 2008, from <http://www.aaup.org/AAUP/comm/rep/A/protecting.htm>.
- American Association of University Professors (AAUP). (2006). Research on Human Subjects: Academic Freedom and the Institutional Review Board. Retrieved May 8, 2008, from <http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm>.
- Brainard, J. (2001). The wrong rules for social science? *The Chronicle of Higher Education*, 47: 21, March 9. Downloaded By: [Goldfarb, Norman M.] At: 20:10 28 July 2008
- Casarett, D., Karlawish, J.H., and Sugarman, J. (2000). Determining when quality improvement initiatives should be considered research: Proposed criteria and potential implications. *JAMA*, 283(17): 2275–2280.
- The Common Rule: Title 45 Code of Federal Regulations, Part 46, Protection of Human Subjects (45 CFR Part 46), revised June 23, 2005. Retrieved May 6, 2008, from <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>.
- Department of Health and Human Services (HHS). (1998). Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure. Retrieved April 2, 2008, from <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>
- De Vries, R., DeBruin, D.A., and Goodgame, A. (2004). Ethics review of social, behavioral, and economic research: Where should we go from here? *Ethics and Behavior*, 14(4): 351–368.
- Ellis, J.B., and Earley, M.A. (2006). Reciprocity and constructions of informed consent: Researching with indigenous populations. *International Journal of Qualitative Methods*, 5(4): 1–9.
- Feeley, M.M. (2007). Legality, social research, and the challenge of institutional review boards. *Law and Society Review*, 41(4): 757–776.
- Giles, J. (2005). Researchers break the rules in frustration at review boards. *Nature*, 438(7065): 136–137.
- Gunsalus, C.K., Bruner, E., Burbules, N.C., et al. (2006). The Illinois White Paper—Improving the System for Protecting Human Subjects: Counteracting IRB Mission Creep. Center for Advanced Study. Retrieved March 19, 2008, from <http://www.law.uiuc.edu/conferences/whitepaper/papers/>.
- Hamburger, P. (2004). The new censorship: Institutional review boards. *The Supreme Court Review*, 2004: 271–354.
- Hoeyer, K., Dahlager, L., and Lynoe, N. (2005). Conflicting notions of research ethics: The mutually challenging traditions of social scientists and medical researchers. *Social Science & Medicine*, 61(8): 1741–1749.
- Howard, J. (2006). Oral history under review. *The Chronicle of Higher Education*, 53(12): 14, Nov. 10.

- Hyman, D.A. (2007). Institutional review boards: Is this the least worst we can do? *Northwestern University Law Review: Symposium: Censorship and Institutional Review Boards*, 101(2): 749–773.
- Jaschik, S. (2005). The sociology of IRBs. *Inside Higher Ed*, Aug. 15. Retrieved May 8, 2008, from <http://insidehighered.com/news/2005/08/15/irb>.
- Katz, J. (2006). Ethical escape routes for underground ethnographers. *American Ethnologist*, 33(4): 499–506.
- Keith-Spiegel, P., and Koocher, G.P. (2005). The IRB paradox: Could the protectors also encourage deceit? *Ethics and Behavior*, 15(4) 339–349.
- Kerr, R.L. (2006). Unconstitutional review board? Considering a first amendment challenge to IRB regulation of journalistic research methods. *Communication Law and Policy*, 11: 393–447.
- Lincoln, Y.S., and Tierney, W.G. (2004). Qualitative research and institutional review boards. *Qualitative Inquiry*, 10: 219–234.
- Miller, F.G., and Emanuel E.J. (2008). Quality-Improvement Research and Informed Consent. *The New England Journal of Medicine*, 358(8): 765–767.
- National Academy of Sciences, Panel on Institutional Review Boards, Surveys, and Social Science Research (NAS). (2003). *Protecting Participants and Facilitating Social and Behavioral Sciences Research*. Constance F. Citro, Daniel R. Ilgen, and Cora B. Marrett, eds. The National Academies Press: Washington, D.C.
- National Bioethics Advisory Commission (NBAC). (2000). Ethical and Policy Issues in the Oversight of Human Subjects, 39th Meeting, April 6. Retrieved March 18, 2008, from <http://bioethics.georgetown.edu/nbac/transcripts/>.
- Nelson, C. (2003). Can E.T. phone home? The brave new world of university surveillance. *Academe*, Sept.--Oct. Retrieved May 8, 2008, from <http://www.aaup.org/AAUP/pubsres/academe/2003/SO/Feat/nels.htm>
- Office for Human Research Protections (OHRP). (2008). OHRP concludes case regarding Johns Hopkins University research on hospital infections, February 15. Retrieved May 6, 2008, from <http://www.hhs.gov/ohrp/news/>.
- Oral history exempted from federal oversight. (2004). *Academe*, Jan/Feb. Retrieved March 24, 2008, from <http://findarticles.com/p/articles/>.
- Pollick, A. (2007). IRBs: Navigating the maze practical advice for working with institutional review boards. *APS Observer*, 20(10). Retrieved March 31, 2008, from <http://www.psychologicalscience.org/observer>.
- Shamoo, A.E. (2007). Deregulating low-risk research. *The Chronicle of Higher Education*, 53, August 3. Retrieved May 6, 2008, from <http://chronicle.com/weekly/v53/i48/48b01601.htm>.
- Shea, C. (2000). Don't talk to the humans: The crackdown on social science research. *Lingua Franca*, 10(6): September, 26–34.
- Stark, L. (2007). Victims in our own minds? IRBs in myth and practice. *Law and Society Review*, 41(4): 777–786.
- Sugarman, J., Getz, K., Speckman, J.L., Byrne, M.M., et al. (2005). The cost of institutional review boards in academic medical centers. *The New England Journal of Medicine*, 352(17): 1825.

Shweder, R.A. (2006). Protecting human subjects and preserving academic freedom: Prospects at the University of Chicago. *American Ethnologist*, 33(4):507–518.

Tolich, M. (2004). Internal confidentiality: When confidentiality assurances fail relational informants. *Qualitative Sociology*, 27(1): 101–106.

Weber, H.R. (2006). Jewell: Olympics allegations still painful. *USA Today*, July 23. Retrieved March 20, 2008, from http://www.usatoday.com/news/nation/2006-07-23-jewell-remembers_x.htm.

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